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**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

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*Ex parte* GABOR BOGYE

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Appeal 2008-1234
Application 09/890,029
Technology Center 1600

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Decided: September 15, 2008

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Before TONI R. SCHEINER, DEMETRA J. MILLS, and ERIC GRIMES, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of reducing risk of thromboembolism caused by gestagen hormones. The Examiner has rejected the claims as indefinite, anticipated, and obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part and enter a new ground of rejection.

## BACKGROUND

"It has been known that the most important side effect of the use of some compositions containing steroid hormones, such as gest[a]gen, is the increased occurrence of thromboembolic diseases" (Spec. 1). The Specification also discloses that "it has become known, that the increase of the homocysteine content in the human plasma is an independent risk factor of arterial and venal thrombosis and embolism" (*id.* at 2) and that "[s]ome compounds (folic acid, vitamin $B_6$, vitamin $B_{12}$, betaine, choline, acetyl cysteine) reduce the homocysteine content of the plasma in case of certain types of hyperhomocysteinaemia" (*id.* at 3).

The Specification discloses that

> the occurrence of thromboembolic diseases which can be correlated with the administration of . . . gest[a]gen type steroid hormone, is greatly due to the plasma homocysteine level increasing activity of the gest[a]gen hormones. . . . [T]his increase of the plasma homocysteine level caused by gest[a]gen hormones can efficiently be reduced or prevented by known homocysteine level reducing agents, e.g. folic acid, vitamin $B_6$, [etc.]

(*Id.* at 3-4.)

## DISCUSSION

### 1. CLAIMS

Claims 9-12, 20, and 25-39 are pending and on appeal. Claims 9 and 20 are representative and read as follows:

9. A method of treating a patient undergoing treatment with a gestagen hormone composition for hormone replacement therapy, for inflammation, for an in vitro fertilization program, for dermatological therapy or for cosmetological treatment to reduce a risk to the patient of thromboembolism induced by taking the gestagen hormone, which comprises the step of administering to the patient simultaneously, previously

or subsequently to taking the gestagen hormone composition a therapeutically effective amount of a plasma homocysteine reducing agent.

20. A method of reducing a risk to an otherwise healthy patient of a thromboembolism induced by administration of a gestagen hormone to said patient comprising the step of administering to the patient simultaneously, previously or subsequently to taking the gestagen hormone composition a therapeutically effective amount of a plasma homocysteine reducing agent.

2. DEFINITENESS

Claims 20, 26-28, 32-35, and 39 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite (Answer 3). The Examiner concludes that "[t]he term 'an otherwise healthy patient' recited in claim 20 renders the claims indefinite as to the patient population encompassed thereby. It is not clear what patients or individual[s] would be considered 'healthy' as recited in the claims." (*Id.*)

Appellant argues that

> [t]he term "otherwise healthy patient" in the case of treatment with hormone for contraception defines a patient who is healthy at the beginning of the hormone treatment and remains healthy in the course of the whole treatment. The term "otherwise healthy patient" in indications other than contraception means that apart from the indication of the hormone therapy the patient is healthy at the beginning of the hormone treatment and remains healthy in the course of the whole treatment.

(Appeal Br. 5.)

While we agree with the Examiner that the phrase "otherwise healthy" can be somewhat ambiguous, we conclude that in the context of the instant claims, its meaning is reasonably clear. Claims are in compliance with

35 U.S.C. § 112, second paragraph, if "the claims, read in light of the specification, reasonably apprise those skilled in the art and are as precise as the subject matter permits." *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385 (Fed. Cir. 1986). "[T]he definiteness of the language employed must be analyzed—not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art." *In re Moore*, 439 F.2d 1232, 1235 (CCPA 1971).

Claim 20 is directed to a method of reducing thromboembolism in a patient who is taking a gestagen hormone. The Specification makes clear that the patient can be taking a gestagen hormone for a variety of reasons: contraception, hormone replacement therapy, antiinflammation, etc. (Spec. 4). The Specification also states that the homocysteine level reducing agent and the gestagen hormone can be included in the same dosage form, "ensuring thereby the simultaneous application of the hormone active ingredient and the 'antidote' acting against the most important side effect of the hormone" (*id.* at 6).

We agree with Appellant that when the claim language is read in light of the Specification, it is reasonably clear that "an otherwise healthy patient" within the scope of the claims is one who is healthy except for whatever reason she is taking a gestagen hormone. The rejection under 35 U.S.C. § 112, second paragraph, is reversed.

3. ANTICIPATION BY SPELLACY OR BUTTERWORTH

Claims 20, 28, 29, 31-33, 35, 37, and 39 stand rejected under 35 U.S.C. § 102(b) as anticipated by Spellacy[1] (Answer 4). Claims 20, 27, 32-35 and 39 stand rejected under 35 U.S.C. § 102(b) as anticipated by Butterworth[2] (Answer 5). The Examiner finds that Spellacy and Butterworth teach administration of vitamin $B_6$ or folic acid, respectively, to women taking progesterone-containing oral contraceptives (Answer 4 and 5).

Appellant argues that the patients treated in Spellacy and Butterworth are not "otherwise healthy," as required by the claims, because the "patients of SPELLACY et al became diabetic in the course of the gestagen treatment" (Appeal Br. 16) and "the patients of BUTTERWORTH et al had cervical dysplasia already at the beginning of the folic acid treatment, therefore, they were not healthy" (*id.* at 17).

The Examiner argues that "otherwise healthy" should be interpreted to mean the patients would be healthy if they were not taking a gestagen hormone (Answer 11). The Examiner concludes that under this interpretation, the references anticipate because the patients in Spellacy and Butterworth took gestagen-containing compositions for contraception, not to treat a preexisting condition, and would have been healthy but for taking the oral contraceptives (*id.*).

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[1] Spellacy et al., *The effects of vitamin $B_6$ on carbohydrate metabolism in women taking steroid contraceptives: Preliminary report*, 6 CONTRACEPTION 265-273 (1972).

[2] Butterworth et al., *Improvement in cervical dysplasia associated with folic acid therapy in users of oral contraceptives*, 35 AMER. J. CLIN. NUTRITION 73-82 (1982).

We do not agree with this interpretation. Individuals who are not taking a gestagen hormone are not within the scope of the instant claims, because such individuals would have no need for treatment to "reduc[e] a risk . . . of thromboembolism induced by administration of a gestagen hormone" (claim 20). Therefore, to consider individuals who are not taking a gestagen hormone to be the baseline for "otherwise healthy" is not consistent with the disclosure in the Specification that the intended patient population is individuals who have an increased risk of thromboembolism as a result of taking a gestagen hormone.

As we interpret the claims, they are directed to a method of treating patients who are healthy except for the reason they are taking a gestagen hormone. The patients in Spellacy and Butterworth developed side-effects from taking progesterone-containing oral contraceptives (Spellacy 265, Butterworth 73). Since the patients were taking a gestagen hormone for the purpose of contraception, and later developed "carbohydrate metabolic abnormalities" (Spellacy 266) or cervical dysplasia (Butterworth 73), we agree with Appellant that the method disclosed in Spellacy and Butterworth is not a method of treating "an otherwise healthy patient" with a plasma homocysteine-reducing agent. We therefore reverse the anticipation rejections based on Spellacy or Butterworth.

4. ANTICIPATION BY KAFRISSEN

Claims 9, 11, 20, 27, 32-36, and 39 stand rejected under 35 U.S.C. § 102(e) as anticipated by Kafrissen[3] (Answer 5). The Examiner finds that Kafrissen teaches a method of administering folic acid, in amounts of 25 µg

[3] Kafrissen et al., U.S. Patent 6,190,693 B1, issued Feb. 20, 2001.

to 1 gram, along with progesterone-containing oral contraceptives or hormone replacement compositions (Answer 5).

We agree with the Examiner's finding. Kafrissen teaches "folic acid-containing pharmaceutical compositions comprising either an oral contraceptive or a hormone replacement composition" (Kafrissen, abstract). The "daily dose of folic acid administered . . . is from about 25 μg to about 1 g" and 1-5 mg/day for reduction of elevated homocysteine levels (*id.* at col. 7, ll. 46-56). The instant Specification discloses that a dosage of folic acid effective to reduce plasma homocysteine levels is 0.5 mg to 5 mg per day (Spec. 6: 25-27). Kafrissen also teaches that conventional oral contraceptives and hormone replacement therapy compositions contain progestin-related compounds ("PRC"), i.e., gestagens (*see id.* at col. 9, l. 30 to col. 10, l. 50; col. 12, ll. 20-65). Thus, Kafrissen discloses the method of claim 9.

Appellant argues that the patients treated in Kafrissen are not healthy because they are "patients for whom the incidence of certain disorders is higher than normal" and "having the risk factors of a disease is not equal to being healthy" (Appeal Br. 7).

This argument is not persuasive. First, claim 9 is not directed to a method of treating a "healthy" or "otherwise healthy" individual: the claim only requires that the patient is "undergoing treatment with a gestagen hormone composition" for one of several enumerated reasons. The claims have not been argued separately and we have selected claim 9 as representative. *See* 37 C.F.R. § 41.37(c)(1)(vii). Since Kafrissen discloses a method of administering folic acid, in the correct amount, to patients taking

a gestagen hormone composition for hormone replacement therapy, it meets the limitations of claim 9.

In any case, we disagree with Appellant's interpretation of the term "healthy." A person is not unhealthy simply because she has a risk factor for a certain condition. The population of people having an elevated risk for a certain disease includes people who have the disease (and are therefore not healthy) as well as people who do not, and might never, have the disease (and are therefore healthy). To give one obvious example, it is well known that people with fair skin are at an elevated risk of skin cancer, but that doesn't mean that no one with fair skin is healthy. None of the references cited by Appellant (Appeal Br. 7-12) support his position by defining "healthy" to exclude people with an elevated risk of a disease.

Appellant also argues that he has submitted a declaration under 37 C.F.R. § 1.131 (originally filed Feb. 9, 2006) that removes Kafrissen as prior art because it "show[s] that he conceived of the invention well before the effective date of KAFRISSEN et al as a reference under 35 USC 102e and then diligently reduced his invention to practice" (Appeal Br. 14-15).

The Examiner replies that a "rejection under 35 USC 102(e) cannot be overcome by a declaration under 37 CFR 1.131 as it is not sufficient to antedate the reference if it is a US patent and teaches the same invention" (Answer 10). The Examiner is mistaken – a Rule 131 declaration can effectively antedate a reference that qualifies under 35 U.S.C. § 102(e). In this case, however, Appellant's declaration is not adequate to overcome Kafrissen.

Rule 131 requires that

> [t]he showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application.

37 C.F.R. § 1.131(b).

Appellant does not assert that he reduced the claimed method to practice prior to the effective date of Kafrissen. To satisfy Rule 131, therefore, he must show conception prior to the effective date of Kafrissen "coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application."

The apparent effective date of Kafrissen is April 17, 1998. Appellant's declaration states that he conceived of the instantly claimed method on June 3, 1996 (Rule 131 declaration, page 1). Appellant attached to the declaration a copy of a data sheet with annotations that, he asserts, shows conception of the instantly claimed method (Rule 131 declaration, page 2).

As evidence of diligence, Appellant attached to the declaration

> a disclosure of the present invention in Hungarian . . . with a certified English translation thereof . . . that I prepared and had notarized after having discussed my invention and its patentability with patent experts in Hungary in summer and autumn of 1998 to corroborate my earlier date of conception and to establish my diligence in seeking its reduction to practice.

(Rule 131 declaration, page 2.) Finally, Appellant declares that the claimed method was constructively reduced to practice when a Hungarian patent application was filed Feb. 1, 1999 (*id.*).

We will assume for present purposes that the Rule 131 declaration provides adequate evidence to show conception of the instantly claimed method on June 3, 1996 and constructive reduction to practice on Feb. 1, 1999. Even so, the declaration does not meet the requirements of Rule 131 because it does not provide the evidence of due diligence required to couple the date of conception to the constructive reduction to practice.

The only evidence of diligence provided in the declaration is an invention disclosure dated Nov. 17, 1998 (Rule 131 declaration, attachment C). According to Appellant, he prepared the disclosure after discussing the "invention and its patentability with patent experts in Hungary in summer and autumn 1998" (*id.*, page 2). Thus, at best the evidence of record shows that Appellant waited at least two years (June 1996 to "summer . . . 1998") after conceiving the instantly claimed method to take any steps to constructively reduce it to practice. A two-year unexplained delay is not "due diligence."

More importantly, Appellant's evidence of diligence is from "summer . . . 1998" and Kafrissen has an apparent effective date of April 17, 1998. Rule 131 requires evidence of "conception of the invention prior to the effective date of the reference coupled with due diligence *from prior to said date* to a subsequent reduction to practice or to the filing of the application." 37 C.F.R. § 1.131(b) (emphasis added). Appellant has provided no evidence of diligence from prior to the effective date of Kafrissen and therefore has not met the requirements of Rule 131.

We affirm the rejection of claim 9 as anticipated by Kafrissen. Claims 11, 20, 27, 32-36, and 39 fall with claim 9 because they were not argued separately. 37 C.F.R. § 41.37(c)(1)(vii).

5. OBVIOUSNESS

Claims 9-12, 20, and 25-39 stand rejected under 35 U.S.C. § 103(a) as obvious in view of Jackson[4] and Fermo[5] (Answer 6). The Examiner finds that Jackson teaches a multivitamin composition containing, among other things, folic acid, vitamin $B_6$, and Vitamin $B_{12}$ intended for use by women in various stages of their lives, but does not "teach the patients taking hormonal composition containing gestagen" (Answer 6).

The Examiner finds that Fermo "teaches hyperhomocysteinemia as pathogenic significant of patients developing thrombosis" (*id.*) and concludes that "[i]t would have been obvious to one of ordinary skill in the art at the time of invention to employ folic acid, vitamin B6, and vitamin B12 to reduce the serum level of homocysteine and thereby the risk of coronary disease in patients taking gestagen composition" (*id.*).

Appellant argues that "[t]here is first of all no disclosure or suggestion in either FERMO et al or JACKSON et al to administer a gestagen hormone together with a plasma homocysteine reducing agent" (Appeal Br. 19).

We will reverse this rejection. The claims are directed to methods of treating patients who are taking a gestagen hormone. The Examiner has expressly found that Jackson does not disclose treating patients taking a gestagen hormone (Answer 6). The Examiner has pointed to no disclosure in Fermo of treating patients taking a gestagen hormone. As we read the reference, Fermo is directed to determining whether patients who have had

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[4] Jackson et al., U.S. Patent 5,654,011, issued Aug. 5, 1997.
[5] Fermo et al., *Prevalence of Moderate Hyperhomocysteinemia in Patients with Early-Onset Venous and Arterial Occlusive Disease*, 123 ANNALS OF INTERNAL MEDICINE 747-753 (1995).

venous or arterial occlusions at a young age have elevated levels of plasma homocysteine.

Because Fermo does not make up for the deficiency of Jackson, the Examiner has not adequately shown that the references would have made obvious the claimed method. The rejection of claims 9-12, 20, and 25-39 as obvious in view of Jackson and Fermo is reversed.

NEW GROUND OF REJECTION

Under the provisions of 37 C.F.R. § 41.50(b), we enter the following new ground of rejection: Claims 9, 11, 12, 20, 27-29, 31-37, and 39 are rejected under 35 U.S.C. § 103(a) as obvious in view of Jackson and Kafrissen. As discussed above, Jackson teaches multivitamin compositions for use by women at different stages of life (Jackson, abstract). The composition for pre-perimenopausal women (i.e., women of childbearing age) includes "about 50 to about 100 mg vitamin $B_6$" (*id.* at col. 2, ll. 46-47). The composition for post-menopausal women includes "about 1.6 to about 10 mg vitamin $B_6$" (*id.* at col. 3, ll. 16-17).

As discussed above, Kafrissen teaches pharmaceutical compositions containing folic acid (25 µg to 1 gram daily dose) along with a gestagen-containing oral contraceptive or a hormone replacement composition (Kafrissen, abstract; col. 7, ll. 46-56; col. 9, l. 30 to col. 10, l. 50; col. 12, ll. 20-65).

Jackson teaches that the disclosed multivitamin "prevent[s] or reduce[s] the risk of fetal neural tube defects, iron deficiency anemia, PMS, osteoporosis, coronary heart disease," etc. in pre-perimenopausal women; i.e., women of childbearing age who would be likely to take oral contraceptives (Jackson, col. 2, ll. 34-40). Jackson teaches that the disclosed

multivitamin "prevent[s] or reduce[s] of the risk of coronary heart disease, some forms of cancer and osteoporosis" in post-menopausal women; i.e., women who would be likely to take hormone replacement compositions. (*Id.* at col. 3, ll. 8-9.)

It would have been obvious to a person of ordinary skill in the art to administer the multivitamin composition disclosed by Jackson to women taking Kafrissen's composition of folic acid combined with either an oral contraceptive or hormone replacement composition, in order to prevent or reduce the risk of certain disorders, as disclosed by Jackson.

As discussed above, the amount of folic acid in Kafrissen's compositions is within the range of therapeutically effective amounts disclosed in the instant Specification (Kafrissen, col. 7, ll. 46-56; Spec. 6: 25-27). The amounts of vitamin $B_6$ in Jackson's compositions are also therapeutically effective amounts, according to the instant Specification. Compare Jackson, col. 2, ll. 46-47 ("about 50 to about 100 mg vitamin $B_6$") and col. 3, ll. 16-17 ("about 1.6 to about 10 mg vitamin $B_6$") with Specification 6: 25-29 ("effective dosage . . . ranges from . . . 10 mg to 300 mg of vitamin $B_6$").

The method suggested by Jackson and Kafrissen meets all the limitations of claims 9, 11, 12, 20, 27-29, 31-37, and 39.

SUMMARY

We reverse the rejections for indefiniteness, obviousness, and anticipation by Spellacy and Butterworth. We affirm the rejection of claims 9, 11, 20, 27, 32-36, and 39 as anticipated by Kafrissen. We enter a new ground of rejection of claims 9, 11, 12, 20, 27-29, 31-37, and 39 as obvious

based on Kafrissen and Jackson. Claims 10, 25, 26, 30, and 38 are not subject to any outstanding rejection.

TIME PERIOD FOR RESPONSE

Regarding the affirmed rejection(s), 37 CFR § 41.52(a)(1) provides that "Appellant may file a single request for rehearing within two months from the date of the original decision of the Board."

In addition to affirming the examiner's rejection(s) of one or more claims, this decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides: "A new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 CFR § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution*. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .
>
> (2) *Request rehearing*. Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

Should the Appellant elect to prosecute further before the examiner pursuant to 37 CFR § 41.50(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the Examiner unless, as a mere incident to the limited

prosecution, the affirmed rejection is overcome.

If the Appellant elects prosecution before the examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for rehearing thereof.

AFFIRMED-IN-PART, 37 C.F.R. § 41.50(b)

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